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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant: Daniel J. DRUCKER et al.

Title: GLP-2 RECEPTOR GENE PROMOTER AND USES THEREOF

Appl. No.: 09/833,740

Filing Date: 04/13/2001

Examiner: Scott David Priebe

Art Unit: 1632

**BRIEF ON APPEAL**

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Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

This Brief on Appeal follows the Notice of Appeal filed October 9, 2003, and is re-filed following the Notice of Non-Compliance of February 12, 2004, the Advisory Action of February 19, 2004, and the Advisory Action of March 31, 2004.

In accordance with 37 C.F.R. § 1.192, this Appeal Brief is being filed in triplicate.

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

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## (1) REAL PARTY IN INTEREST

The real party in interest is NPS ALLELIX Corp, the assignee of U.S. Application No. 09/833,740.

## (2) RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative, and Assignee know of no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

## (3) STATUS OF CLAIMS

Claims 1-11 are pending in the application. Claims 6-8 were withdrawn from consideration, as being directed to a non-elected invention. Claims 1-5 and 9-11 were finally rejected and are appealed. A clean copy of claims 1-5 and 9-11 is set forth in Appendix A.

## (4) STATUS OF AMENDMENTS

The Examiner did not enter the proposed amendments to the specification and claims submitted with the response filed October 9, 2003, or the proposed amendments to the claims submitted with the brief filed January 9, 2004. The Examiner did enter the amendments submitted February 6, 2004, but maintained a rejection under 35 U.S.C. §112 and 35 U.S.C. §132.

The Examiner rejected the Appeal Brief filed January 9, 2004 because the brief did not contain a correct copy of the appealed claims. A replacement brief was filed

March 5, 2004, the examiner rejected that brief because the brief did not address the new matter rejection. The instant brief addresses that rejection.

A proposed amendment to claim 1 is submitted in conjunction with this brief. In the telephone conversation on April 30, 2004, the examiner stated that he would enter the proposed claim amendment for purposes of appeal. A marked up copy of the claims, showing the proposed amendments, is set forth in Appendix B and a clean copy of the claims is provided in Appendix C. The amendments are believed to overcome at least one aspect of the new matter rejection and place the claims in better form for allowance.

## (5) SUMMARY OF INVENTION

The invention is directed to a recombinant DNA construct comprising a promoter region of a GLP-2R gene linked with a heterologous gene of interest. The GLP-2R gene is expressed in a highly tissue specific manner predominantly in the gut endocrine cells and the Central Nervous System (CNS). Specification, paragraph 8. The function of the GLP-2R gene in the CNS has not been identified, but it is known that the gene functions as a growth factor in gastrointestinal tissues. Specification, paragraphs 8 and 2. Prior to the present invention, the mechanisms behind the GLP-2R gene activity were poorly defined. Specification, paragraph 9. The present invention identifies the previously unrecognized function of the 5'-flanking region as the tissue-specific promoter for the GLP-2R gene. Specification, paragraphs 42-43. By operably linking this promoter region with a target gene of interest, tissue-specific expression of the gene can be achieved. If the gene is a reporter

gene, the construct permits detection of GLP-2R gene activity. Specification, paragraphs 10 and 12.

As stated above, the present invention teaches that the GLP-2R promoter region is located in the 5'-flanking region upstream of the transcription start site of the GLP-2R gene. Specification, paragraph 43. The specification confirms this location of the promoter region for mouse, rat, and human GLP-2R genes. Specification, paragraph 101. The specification and figures compare the mouse, human and rat regions of the GLP-2R gene upstream and downstream of the transcription start site and demonstrate the similarity of these regions across mammalian species. Specification, paragraph 104 and Figure 7b. Specifically, the specification and figures show the similarity of the upstream regions of the mouse and human sequences and of the downstream regions of the mouse, human and rat sequences. See Figure 7b.

The promoter region included in the claimed construct comprises at least 1,000 nucleotide bases of the murine sequence of SEQ ID NO:1 or of a mammalian homolog of that sequence. As taught in the specification, the entire genomic sequence for the mouse and human GLP-2R genes are publicly available in GenBank under Accession Nos. AC016464 and AC069006, respectively. Specification, paragraph 97. Moreover, the invention provides, in the Figures and the Sequence Listing, partial nucleotide sequences for the mouse and human GLP-2R promoter regions. *See* Figure 1 and Figure 7b.

## (6) ISSUES

The instant appeal presents the following issues for review:

I. Does the specification satisfy the written description and definiteness requirements with respect to claims 1-5, which recite a recombinant DNA construct comprising a promoter region of a GLP-2R gene which comprises at least the last 1,000 nucleotides of either the murine nucleotide sequence of SEQ ID NO:1 or a mammalian homolog thereof, where the specification describes partial nucleotide sequences for the murine and human GLP-2R promoter regions, teaches the location of the promoter region in the GLP-2R gene, and discloses the correlation between the location of the sequence and its function?

II. Does the specification satisfy the written description and definiteness requirements with respect to claim 9, which depends from claim 1 and further defines the promoter region as a human homolog comprising at least residues -1 to -203 of Figure 7b, where the specification describes in Figure 7b and SEQ ID NO:7 nucleotides comprised in the human 5'-flanking and 5'-untranslated sequences comprised in the promoter region of the human GLP-2R gene, teaches the location of the promoter region in the known human GLP-2R gene, and discloses the correlation between the location of the sequence and its function?

III. Does the specification satisfy the written description and definiteness requirements with respect to claim 10, which depends from claim 9 and further defines the promoter region as comprising from 1.5 kb to 10.6 kb of the murine GLP-

2R receptor promoter, where the sequence set forth in Figure 1 and SEQ ID NO:1 includes at least 1.5 kb of the murine GLP-2R receptor promoter, the specification includes an example of a 10.6 kb promoter region in Example 2, where the murine and human GLP-2R genes *per se* are known in the art, and where the specification teaches the location of the promoter region in the known murine GLP-2R gene and discloses the correlation between the location of the sequence and its function?

IV. Does the specification satisfy the written description and definiteness requirements with respect to claim 11, which depends from claim 10 and further defines the promoter region as comprising the nucleotide sequence of SEQ ID NO:1, where the specification sets forth that sequence in the Sequence Listing and in Figure 1, where the murine GLP-2R gene *per se* is known in the art, and where the specification teaches the location of the promoter region in the known murine GLP-2R gene and discloses the correlation between the location of the sequence and its function?

V. Do the amendments to independent claims 1 and 9-11 introduce new matter where the specification defines the promoter region as comprising the nucleotide sequence of SEQ ID NO:1, describes partial nucleotide sequences for the murine and human GLP-2R promoter regions, teaches the location of the promoter region in the GLP-2R gene, discloses the correlation between the location of the sequence and its function, and sets forth partial sequences in the Sequence Listing and in Figures 1, 2 and 7b?

## (7) GROUPING OF CLAIMS

Claims 1-5 and 9-11 were rejected under the first and second paragraphs of 35 U.S.C. §112. For the purpose of this appeal only, and for each ground of rejection, claims 1-5 stand or fall together, claim 9 stands or falls alone, claim 10 stands or falls alone, and claim 11 stands or falls alone. Argument for the separate patentability of claims 1-5, 9, 10 and 11 is set forth in section (8), subsections II-V, below.

## (8) ARGUMENT

The rejection of claims 1-5 and 9-11 under the first and second paragraphs of 35 U.S.C. § 112 should be reversed because the claims satisfy the written description and definiteness requirements of the statute. Likewise, the rejection of the amended claims under 35 U.S.C. §112, first paragraph, and 35 U.S.C. § 132 should be reversed because the amended claims are fully supported by the application as filed. The final rejections of the claims are based on a misunderstanding of the current law on written description, as applied to biotechnology inventions, and on a misunderstanding of the claims and the description in the specification.

### I. INTRODUCTION

#### A. The Current Law on the Written Description Requirement

The first paragraph of § 112 requires that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (1994). Application of the written description requirement to biotechnology inventions is an evolving area of law. As set forth in *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), an adequate written description of DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties." In *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), the Federal Circuit determined that "a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description because it does not distinguish the claimed genus from others, except by function." The court noted that such a description "does not define any structural features commonly possessed by members of the genus that distinguish them from others." *Id.* The court indicated that "a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence . . . or of a recitation of structural features common to the members of the genus." *Id.* at 1569.

More recently, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002), the Federal Circuit clarified the holding of *Lilly*, stating that "[i]t is not correct that all functional descriptions of genetic material fail to meet the written description requirement." The court adopted the principle reflected in the U.S. Patent Office Written Description Guidelines that the written description requirement can be satisfied by the disclosure of a functional characteristic "coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Id.* at 964. The court held further that the disclosure of several species (DNA sequences) within the claimed genus (which was defined in functional terms)

would provide sufficient support for the claimed genus if the disclosed species "are representative of the scope of the genus claims." *Id.* at 967.

**B. The Written Description Requirement is Met in the Present Case**

The written description rejection on appeal is inconsistent with the prevailing case law set forth above. Page 6 of the Final Office Action reveals the incorrect basis of the rejection, asserting that the written description requirement is not met because "the instant specification fails to provide [the claimed] sequences *as required for [a] nucleic acid with a specified function*" (emphasis added). Additionally, page 9 of the previous office action (mailed November 15, 2002) specifically states that amending the claims to include the specific nucleotides of the promoter region of SEQ ID NO. 1 would satisfy both the written description and definiteness requirements. This rationale is plainly incorrect as a matter of law, particularly in view of *Enzo*, which holds that a nucleotide sequence is not required in order to satisfy the written description requirement in all biotechnology cases.

As demonstrated below, the instant specification satisfies the written description requirement in accordance with *Enzo*. The specification describes structural characteristics of several species within the genus of the recited GLP-2R promoter regions, and also discloses a correlation between the function of the promoter regions and their structures. Accordingly, the written description requirement is satisfied, and the § 112, first paragraph rejection of claims 1-5, 9, 10 and 11 should be reversed.

**C. The Current Law on the Definiteness Requirement**

The second paragraph of § 112 requires that:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As stated in *Utah Medical Products v. Graphic Controls Corp.*, 350 F.3d 1376, 1381 (2003), this paragraph "demands nothing more" than that "the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention."

**D. The Definiteness Requirement is Met in the Present Case**

The Examiner's § 112, second paragraph rejection appears to be intertwined with the § 112, first paragraph rejection. *See generally*, Office Action mailed November 15, 2002. Appellants understand that the indefiniteness rejection is based on an assertion that the claims are indefinite because they do not recite the specific nucleic acids that comprise the promoter region included in the claimed construct. The definiteness requirement, however, does not demand recitation of a specific nucleotide sequence. Additionally, Appellants' understand the indefiniteness rejection to be based on the Examiner's uncertainty as to the number of nucleic acids from the promoter region needed to maintain the promoter region's ability to function with requisite similarity to an endogenous GLP-2R promoter. The instant claims,

however, address the Examiner's concerns by reciting a minimum number of nucleotides for the promoter region. Thus, the instant claims satisfy the definiteness requirement, and the § 112, second paragraph rejection of claims 1-5, 9, 10 and 11 should be reversed.

## II. THE REJECTION OF CLAIMS 1-5 UNDER THE FIRST AND SECOND PARAGRAPHS OF §112 SHOULD BE REVERSED BECAUSE THE WRITTEN DESCRIPTION AND DEFINITENESS REQUIREMENTS ARE SATISFIED

Claims 1-5 satisfy the written description and definiteness requirements of §112 because the disclosure of the specification shows the inventor's possession of the invention and because the claims reasonably apprise those skilled in the art of the scope of the invention.

### A. Claims 1-5 Are Adequately Described by the Specification

Claim 1 recites a recombinant DNA construct comprising a promoter region of a GLP-2R gene which comprises at least the last 1,000 nucleotides of either the murine nucleotide sequence of SEQ ID NO:1 or a mammalian homolog thereof. In the proposed amendment submitted herewith, Appellants propose amending this claim to recite the last 1,000 nucleotides "upstream of the transcription start site." Claim 2 depends from claim 1 and further defines the promoter region as being selected from the promoter region of the mouse GLP-2 receptor gene, the promoter region of a homolog of the mouse GLP-2 receptor gene, or a variant of such promoter regions that incorporates a truncation, insertion, deletion, or addition and retains the function of a GLP-2 receptor gene promoter region. Claim 3 depends from claim 1 and defines the heterologous gene as being a reporter gene. Claim 4 depends from claim 1 and defines the heterologous gene as encoding a therapeutic protein. Claim 5 depends from claim 1, and recites a cell incorporating the construct of claim 1.

Because claim 1 is believed to be the broadest of claims 1-5, Appellants will focus their arguments on the written description and definiteness of that claim.

The U.S. Patent Office Written Description Guidelines provide that the written description requirement is satisfied by a disclosure of "sufficiently detailed relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Guidelines, 66 Fed. Reg. 1099 at 1106. The Federal Circuit approved this standard in *Enzo*, where it stated that the written description requirement can be satisfied by the disclosure of a functional characteristic "coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." *Enzo*, 323 F.3d at 964. Applying this standard to the present case, reveals that the written description requirement is satisfied with respect to claims 1-5.

As recited in claim 1, the promoter regions comprise at least the last 1,000 nucleotides of either the murine nucleotide sequence of SEQ ID NO:1 or a mammalian homolog thereof. The specification provides a description of the partial structure of such promoter regions along with other physical properties and functional characteristics and describes a correlation between function and structure.

The specification sets forth a partial structure (nucleotide sequence) for the murine GLP-2R promoter region (SEQ ID NO:1 and Figure 1), which includes at least 1.5 kb of the murine GLP-2R promoter region. The specification also sets forth a partial structure (nucleotide sequence) for the human homolog of the murine GLP-2R promoter region (SEQ ID NO:7 and Figures 7b), which includes at least 202 nucleotides of the human GLP-2R

promoter region. Thus, the specification specifically discloses a partial structure for the recited murine promoter region and for a mammalian (human) homolog thereof. (As taught in the specification, the murine and human genomic GLP-2R sequences are known.) The specification and Figure 7b also show the homology of the mouse and human promoter regions.

The specification also describes another physical property of the inventive promoter regions: the location of the promoter region on the GLP-2R gene. Figure 7b shows the location of the mouse, human and rat promoter regions within the GLP-2R genes. As shown in this Figure and taught in the specification, the promoter region is located in the 5'-flanking region upstream of the transcription start site of the GLP-2R gene. Specification, paragraph 43. (Although the Figure does not set forth the nucleotide sequence of the rat promoter region, it does teach where the region is on the rat genome and shows homology between the mouse, human and rat sequences in the coding region of the GLP-2R gene.) In the proposed language for claim 1, the phrase "upstream of the transcription start site" was added to further clarify the location of the promoter region on the GLP-2R gene as taught in the specification.

The specification also discloses a correlation between the physical property of the claimed promoter regions and their function. Specifically, the specification teaches the correlation between the nucleotide sequences located in the 5'-flanking region upstream of the transcription start site of the GLP-2R gene and the tissue-specific promoter function of the claimed promoter regions. Specification, paragraph 43.

Thus, the specification as a whole satisfies the written description requirement with regard to claim 1 by identifying the region on the GLP-2R gene that correlates with the tissue-specific promoter function, setting forth partial nucleotide sequences of the murine and

human promoter regions, and demonstrating homology between the murine and human promoter regions. The specification also teaches the conserved nature of the promoter region sequences across the mammalian species. The specification shows the homology between the murine, human, and rat GLP-2R sequences just downstream of the promoter regions, in the coding regions. Specification, Figure 7b. Although this teaching does not directly prove that the rat promoter region is homologous to the murine and human promoter regions, those skilled in the art reasonably would expect homology in the promoter regions from the illustrated homology in the coding regions. Taken as a whole, therefore, the specification conveys appellants' possession of the full scope of the invention recited in claim 1, *i.e.*, constructs comprising a promoter region of a GLP-2R gene comprising at least the last 1,000 nucleotides of the murine sequence of SEQ ID NO:1 or of a mammalian homolog thereof. Moreover, the specification as a whole conveys appellant's possession of the full scope of the invention recited in proposed claim 1, *i.e.*, constructs comprising a promoter region of a GLP-2R gene comprising at least the last 1,000 nucleotide upstream of the transcription start site of the murine sequence of SEQ ID NO:1 or of a mammalian homolog thereof.

The foregoing demonstrates the error of the written description rejection of claims 1-5. The Examiner incorrectly applied *Lilly* by requiring a complete nucleotide sequence to satisfy the written description requirement for claims 1-5. See Final Office action mailed 04/09/2003, page 6. As set forth in *Enzo*, *Lilly* holds that the written description requirement is not satisfied when "a gene material has been defined only by a statement of function or result," *Enzo*, 323 F.3d at 963-64, but the written description requirement does not demand the disclosure of a nucleotide sequence for all claims to genetic material.

At the outset, Appellants emphasize that the instant claims do not define the promoter region only by its function. Although the claims include functional language, reciting a "promoter region," they also include structural language, reciting that the promoter sequence comprises "at least the last 1,000 nucleotides of . . . SEQ ID NO:1 . . . or a mammalian homolog [thereof.]" This language alone distinguishes the present case from *Lilly*, where the claims were directed to "a microorganism containing a human insulin cDNA" without any further structural definition. *Enzo*, 323 F.3d at 964. The proposed language for claim 1 further distinguishes this case from *Lilly* by providing additional structural definition for the claimed GLP-2R promoter region with the language "at least the last 1,000 nucleotides upstream of the transcription start site."

As explained in *Enzo*, the Lilly disclosure was defective because "the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics." *Enzo*, 323 F.3d at 964. As demonstrated above, however, the present specification describes the claimed promoter regions with reference to both structural and physical characteristics. Where the Lilly disclosure "did not set forth any common features possessed by members of the claimed genus," *id.* at 967, the present specification teaches the location of the promoter region in the GLP-2R gene and demonstrates sequence homology between the claimed mammalian homologs. Where the Lilly disclosure did not "describe a sufficient number of species within the very broad genus" (*id.*), the present specification describes three representative species within the claimed genus (mouse, human and rat) and discloses partial nucleotide sequences for the promoter region of two species (mouse and human) and identifies the location of the promoter region for the third species (rat) relative to its disclosed coding region. The present

specification therefore provides much more than the bare functional description set forth in the Lilly disclosure, and meets the written description requirement. Accordingly, the § 112, first paragraph rejection of claims 1-5 should be reversed.

**B. Claims 1-5 Meet The Definiteness Requirement**

Claims 1-5 meet the definiteness requirement because they particularly point out and distinctly recite the claimed subject matter.

Instant claim 1, believed to be the broadest claim on appeal, reasonably apprises those skilled in the art of the scope of the invention by defining the promoter region of the claimed construct by function ("promoter region of a GLP-2R gene") and structure (comprising "at least the last 1000 nucleotides of . . . SEQ ID NO:1 . . . or a mammalian homolog [thereof]"). The proposed language for claim 1 provides additional structural definition claiming "at least the last 1,000 nucleotides upstream of the transcription start site of . . . SEQ ID NO:1 . . . or a mammalian homolog [thereof]." Claims 2-5 and 9-11 provide an even more circumscribed description of the claimed invention. Although the Examiner asserts that the length of the claimed promoter region required to function as such is unclear, the claims themselves address this concern by reciting that the promoter region comprises at least 1,000 nucleotides. Additionally, the Examiner asserts that the sequences necessary to provide for the correct functioning of the promoter region of the GLP-2R gene are not identified. However, the claims themselves recite a functional promoter region: a promoter region comprising at least the last 1000 nucleotides of SEQ ID NO:1 or a mammalian homolog thereof. Further, the proposed language for claim 1 recites an even more clearly defined functional promoter region: a promoter region comprising at least the last 1000 nucleotides upstream of the transcription start site of SEQ ID NO:1 or a mammalian homolog thereof.

The Examiner also questions how much functional similarity between the endogenous GLP-2R promoter and the claimed promoter is necessary for the claimed promoter to qualify as "a promoter region of a GLP-2R gene." The Examiner overlooks the teachings in the specification regarding the function of the claimed promoter regions. As taught in the specification, a promoter region with the recited structural (sequence) characteristics will have the requisite functional similarity to the endogenous GLP-2R promoter. Example 7 and Figures 8a, b, and c show that there is a high degree of similarity between the function of a 1.5 kb promoter region and the endogenous GLP-2R promoter. In fact, the 1.5 kb promoter is shown to be active in nine out of ten tissues where the endogenous GLP-2R promoter is active. Specification, paragraph 123. These teachings indicate that the recited promoter regions, comprising at least 1,000 nucleotides, will have the requisite functional characteristics. Further, these teachings indicate that the proposed language in claim 1 for a promoter region, comprising "at least the last 1,000 nucleotides upstream of the transcription start site", will have the requisite functional characteristics.

Because the claim language, read in the context of the specification, reasonably apprises those skilled in the art of the scope of the invention, the § 112, second paragraph rejection of claims 1-5 should be reversed.

III. THE REJECTION OF CLAIM 9 UNDER THE FIRST AND SECOND PARAGRAPHS OF §112 SHOULD BE REVERSED BECAUSE THE WRITTEN DESCRIPTION AND DEFINITENESS REQUIREMENTS ARE SATISFIED

Claim 9 depends from claim 1 and further defines the promoter region of the claimed construct as being a human homolog and as comprising at least residues -1 to -203 of SEQ ID NO:7 of the Sequence Listing thereby conforming to current Patent Office practice of reciting

sequences by SEQ ID NO. Claim 9 is separately patentable from claims 1-5, 10 and 11, and meets the written description and enablement requirements for the reasons set forth below.

**A. Claim 9 Meets the Written Description Requirement**

The subject matter of claim 9 is fully described in the specification because the specification sets forth the recited sequence and teaches that the invention includes promoter regions comprising that sequence. Specification, paragraph 45. The specification also teaches that the human GLP-2R genomic sequence is known. Specification, paragraphs 47 and 97. The specification satisfies *Enzo* with respect to claim 9 because the specification provides a partial structure for the claimed promoter regions in residues -1 to -203 of the sequence depicted in Figure 7b, discloses another physical property of the claimed promoter regions by teaching the location of the promoter region within the known human GLP-2R gene (in the 5'-flanking region), and discloses a correlation between the physical and functional properties by teaching that the nucleotide sequence at that location is responsible for the tissue-specific promoter function.

Contrary to the Examiner's position as reflected in the rejection of this claim, the rationale of *Lilly* does not apply to claim 9, because claim 9 does not define the promoter region by function only. In fact, claim 9 recites that the promoter region comprises a specific sequence set forth in the specification. As demonstrated above, the specification describes the invention of claim 9 in sufficient detail to satisfy the written description requirement as explained in *Enzo*. Accordingly, the §112, first paragraph rejection of claim 9 should be reversed.

### B. Claim 9 Meets The Definiteness Requirement

Claim 9 meets the definiteness requirement of § 112 because it clearly and distinctly defines the claimed invention. Claim 9 recites that the claimed promoter region comprises a specific nucleotide sequence that is expressly set forth in the specification. Although the promoter region includes additional nucleotide sequences, the recitation of this sequence, coupled with the teachings in the specification of the location of the promoter region on the GLP-2R gene, the knowledge in the art of the murine and human GLP-2R genomic sequences, and other teachings regarding the murine, human and rat GLP-2R promoter regions amply apprise those skilled in the art of the scope of the invention recited in claim 9. Accordingly, Appellants' respectfully request the reversal of this rejection.

## IV. THE REJECTION OF CLAIM 10 UNDER THE FIRST AND SECOND PARAGRAPHS OF §112 SHOULD BE REVERSED BECAUSE THE WRITTEN DESCRIPTION AND DEFINITENESS REQUIREMENTS ARE SATISFIED

Claim 10 further defines the promoter region of the claimed construct as comprising from 1.5 kb to 10.6 kb of the murine GLP-2R promoter. Claim 10 currently depends from claim 1. Claim 10 is separately patentable from claims 1-5, 9 and 11, and meets the written description and enablement requirements for the reasons set forth below.

### A. Claim 10 Meets the Written Description Requirement

The subject matter of claim 10 is fully described by the specification. The specification expressly sets forth at least 1.5 kb of the nucleotide sequence of the murine GLP-2R promoter region in Figures 1 and SEQ ID NO: 1. In Example 5, an approximately 1.5 kb promoter fragment of the murine GLP-2R gene containing 5'-flanking and 5'-untranslated sequences is ligated upstream of a lacZ gene and compared with the

expression of the endogenous murine GLP-2R gene. Specification, paragraph 106. The specification also describes a 10.6 kb promoter region. Example 2 illustrates an extended promoter region comprising 10.6 kb of the murine GLP-2R promoter region cloned into a promoterless-nls-lacZ encoding vector. Specification paragraph, 82. The specification further teaches the location of the promoter region (i.e., in the 5'-flanking region upstream of the transcription start site) and the GenBank Accession No. for the murine GLP-2R genomic sequence, and teaches that the sequence at that location is responsible for the tissue-specific promoter function of the murine GLP-2R promoter. Specification, paragraph 43.

The specification satisfies *Enzo* with respect to claim 10 because the specification provides a partial structure for the claimed promoter regions in Figures 1 and 7b and SEQ ID NO: 1 , discloses another physical property of the claimed promoter regions by teaching the location of the promoter region within the known murine GLP-2R gene, and discloses the correlation between the nucleotides at that location and their function as a tissue-specific promoter.

Contrary to the Examiner's position as reflected in the rejection of this claim, the rationale of *Lilly* does not apply to claim 10, because claim 10 does not define the promoter region by function only. As demonstrated above, the specification describes the invention of claim 10 in sufficient detail to satisfy the written description requirement as explained in *Enzo*. Accordingly, the §112, first paragraph rejection of claim 10 should be reversed.

**B. Claim 10 Meets The Definiteness Requirement**

Claim 10 meets the definiteness requirement of § 112 because it clearly and distinctly defines the claimed invention. Claim 10 recites that the claimed promoter region comprises from 1.5 to 10.6 kb of the murine GLP-2R promoter. The genomic murine GLP-2R sequences is known, and the GenBank Accession No. for that sequence is set forth in the specification. The specification also discloses at least 1.5 kb of the nucleotide sequence of the murine GLP-2R promoter region (see, e.g., Figures 1 and 7b and SEQ ID NO: 1). Thus, the language of claim 10 read in light of the specification reasonably apprises those skilled in the art of the scope of the claim, as required by §112, second paragraph.

The Final Office Action states that claim 10 does not meet the written description requirement because "the specification does not describe or disclose 10.6 kb of murine promoter in sufficient detail." That assertion is not correct. Example 2 at paragraph 82 of the instant specification describes a 10.6 kb promoter region of the GLP-2R gene and specifies the insertion of this 10.6 kb promoter region into a construct containing the nlslacZ reporter gene. Further, the construct created in Example 2 is used to establish transgenic animals. Specification, paragraph 82.

Appellants therefore respectfully request that the indefiniteness rejection of claim 10 be reversed.

## V. THE REJECTION OF CLAIM 11 UNDER THE FIRST AND SECOND PARAGRAPHS OF §112 SHOULD BE REVERSED BECAUSE THE WRITTEN DESCRIPTION AND DEFINITENESS REQUIREMENTS ARE SATISFIED

Claim 11 depends from claim 10, and further defines the promoter region as comprising SEQ ID NO:1. Claim 11 is separately patentable from claims 1-5, 9 and 10, and meets the written description and enablement requirements for the reasons set forth below.

### A. Claim 11 Meets the Written Description Requirement

The subject matter of claim 11 is fully described by the specification because the specification sets forth the recited sequence and teaches that the invention includes promoter regions comprising that sequence. Specification, paragraph 44. The specification also teaches that the murine GLP-2R genomic sequence is known. Specification, paragraph 97. The specification satisfies *Enzo* with respect to claim 11 because the specification provides a partial structure for the claimed promoter regions in SEQ ID NO:1, discloses another physical property of the claimed promoter regions by teaching the location of the promoter region within the known murine GLP-2R gene (in the 5'-flanking region), and discloses a correlation between the physical and functional properties by teaching that the nucleotide sequence at that location is responsible for the tissue-specific promoter function.

Contrary to the Examiner's position as reflected in the rejection of this claim, the rationale of *Lilly* does not apply to claim 11, because claim 11 does not define the promoter region by function only. In fact, claim 11 recites that the promoter region comprises a specific sequence set forth in the specification. As demonstrated above, the specification describes the invention of claim 11 in sufficient detail to satisfy the written description requirement as explained in *Enzo*. Accordingly, the §112, first paragraph rejection of claim 11 should be reversed.

**B. Claim 11 Meets The Definiteness Requirement**

Claim 11 meets the definiteness requirement of § 112 because it clearly and distinctly defines the claimed invention. Claim 11 recites that the claimed promoter region comprises a specific nucleotide sequence that is expressly set forth in the specification. Although the promoter region includes additional nucleotide sequences, the recitation of this sequence, coupled with the teachings in the specification of the location of the promoter region on the GLP-2R gene, the knowledge in the art of the murine and human GLP-2R genomic sequences, and other teachings regarding the murine, human and rat GLP-2R promoter regions amply apprise those skilled in the art of the scope of the invention recited in claim 11. Accordingly, Appellants' respectfully request the reversal of this rejection.

## VI. THE REJECTION OF CLAIMS 1 AND 9-11 UNDER THE FIRST PARAGRAPH OF §112 AND UNDER 35 USC § 132 SHOULD BE REVERSED BECAUSE THE AMENDED CLAIMS DO NOT INTRODUCE NEW MATTER

Claims 1-5 are separately patentable from claims 9, 10 and 11. Claim 9 is separately patentable from claims 1-5, 10 and 11. Claim 10 is separately patentable from claims 1-5, 9 and 11. Claim 11 is separately patentable from claims 1-5, 9 and 10. As set forth below, the amendments to claims 1 and 9-11 do not introduce new matter under 35 USC §132 because the specification fully supports the claim limitations of claims 1 and 9-11.

The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application's filing date. *TurboCare Div. Of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001). Section 132 states that "no amendments shall introduce new matter into the disclosure of the invention." However, the Federal Circuit has determined that the claimed invention does not

have to be described in ipsis verbis in order to satisfy the description requirement of § 112. *Wagoner v. Barger*, 463 F.2d 1377, 1380 (Fed. Cir. 1972). Instead, "it is the essence of the original disclosure" that determines whether an amended claim limitation contains new matter. *In Re Richard F. Wright,* 866 F.2d 422 (Fed. Cir. 1989).

**A. Amended Claim 1 Does Not Introduce New Matter**

Amended claim 1 does not introduce new matter because the specification as a whole supports the claim limitations recited in both the current version and the proposed version of claim 1. Proposed claim 1 recites "a recombinant DNA construct, comprising a promoter region of a GLP-2 receptor gene and linked for expression therewith, a heterologous gene of interest, wherein the promoter region comprises at least the last 1,000 nucleotides upstream of the transcription start site of (A) the murine nucleotide sequence of SEQ ID NO. 1 or (B) a mammalian homolog of said murine nucleotide sequence." The examiner questions whether the recitations "at least the last 1,000 nucleotides" and "mammalian homolog" are supported by the specification. These recitations are supported by the teachings that identify the location, structure and function of the promoter region on the GLP-2R gene, and provide partial nucleotide sequences of the murine and human promoter regions.

With regard to the first recitation, "at least the last 1000 nucleotides," appellants have added the phrase "upstream of the transcription start site" to proposed claim 1 to more closely conform to the specification. The specification specifically describes the structure of the promoter region as comprising at least 1000 bases upstream of the transcription start site. Specification, paragraph 43. Further, the essence of the original disclosure supports this phrase by describing a partial nucleotide sequence for both the murine GLP-2R promoter region (SEQ ID NO:1 and Figure 1) and for the human homolog of the murine GLP-2R

promoter region (SEQ ID NO:7 and Figures 7b). Additionally the specification teaches one of skill in the art how to obtain the entire GLP-2R promoter region in the mouse, rat and human. Specification, paragraphs 47-60.

The specification also supports the phrase "mammalian homolog" by demonstrating the homology between the murine and human promoter regions and describing the conserved nature of the promoter region sequences across the mammalian species. Specification, paragraphs 45, 46, 96, 101, and 104. Additional support is provided in the specification where the murine, human, and rat GLP-2R sequences just downstream of the promoter regions are compared in Figure 7b.

Therefore, because the specification as a whole supports the invention recited in claim 1, claim 1 does not introduce new matter. Accordingly, this rejection should be reversed.

**B. Amended Claim 9 Does Not Introduce New Matter**

Claim 9 does not introduce new matter because the specification supports the recited claim limitations. Claim 9 recites "a recombinant DNA construct according to claim 1, wherein said promoter region is a mammalian homolog which is a human homolog comprising at least residues -1 to -203 illustrated in Figure 7b (bases 1-201 of SEQ ID NO:7)." The examiner asserted that the paragraphs previously cited by Appellants did not support claim 9's recited limitations. The examiner further objected to the SEQ ID NO recited in the claim. Appellants assert that the following paragraphs support the limitations in claim 9 and that the correct SEQ ID NO is now referenced in the claim language.

Claim 9 recites "a DNA construct." The specification specifically teaches the creation of a DNA construct. Specification, paragraph 11.

Claim 9 also recites that this construct contains a "promoter region." The specification teaches the general structure, location, and function of the GLP-2R promoter region. Specification, paragraph 43.

Additionally, claim 9 recites that the promoter region is a "mammalian homolog." The specification specifically teaches that the invention extends to mammalian homologs, showing that the GLP-2R promoter region can be obtained from other mammals, including humans and rats. Specification, paragraphs 45-47. The specification also supports this phrase by demonstrating the homology between the murine and human promoter regions, describing the conserved nature of the promoter region sequences across the mammalian species, and comparing the murine, human, and rat GLP-2R sequences just downstream of the promoter regions in Figure 7b. Specification, paragraphs 45, 46, 96, 101, and 104.

Finally, claim 9 recites that the mammalian homolog is a "human homolog" comprising "at least residues -1 to -203 illustrated in Figure 7b (bases 1-201 of SEQ ID NO:7)." The specification support this recitation because it provides the partial sequence for the human GLP-2R promoter region, specifically nucleotide residues -1 to -203 in Figure 7b and the corresponding nucleotide residues 1-201 in SEQ ID NO: 7. Specification, paragraph 47 and 97.

Additionally, Appellants previously corrected the SEQ ID NO recited in claim 9 to recite SEQ. ID. NO.:7. This is the correct SEQ ID NO for the human promoter region and corresponds with the application's sequence listing.

Therefore, because the specification supports the limitations recited in claim 9, claim 9 does not introduce new matter under 35 USC § 132. Accordingly, this rejection should be reversed.

**C. Amended Claim 10 Does Not Introduce New Matter**

Claim 10 does not introduce new matter because the specification supports the limitations recited in claim 10. Claim 10 recites "a recombinant DNA construct according to claim 1, wherein the promoter region comprises from 1.5 kb to 10.6kb of the murine GLP-2 receptor promoter." The examiner asserted that the paragraphs previously cited by Appellants do not support claim 10's recited limitations.

Claim 10 recites "a DNA construct" that contains a "promoter region." The specification specifically describes the location, function and structure of the GLP-2 receptor promoter region as well as teaches the use of this promoter region in a DNA construct. Specification, paragraphs 11 and 43.

Claim 10 also recites that the promoter region "comprises from 1.5kb to 10.6kb of the murine GLP-2 receptor promoter." With regard to this recitation, the specification specifically provides an example of a murine DNA construct containing a 1.5kb GLP-2R promoter region. Specification, paragraphs 44 and 81. Additionally, the specification provides an example of a murine DNA construct containing a 10.6kb murine GLP-2R promoter region. Specification, paragraph 82. More generally, the specification provides a partial murine nucleotide sequence as shown in Figure 1 and SEQ ID NO: 1. Specification, paragraph 43.

Therefore, the specification supports the recitations of claim 10, and claim 10 does not introduce new matter under 35 U.S.C. § 132. Accordingly, this rejection should be reversed.

**D. Amended Claim 11 Does Not Introduce New Matter**

Claim 11 does not recite new matter because the specification supports the claim limitations recited in claim 11. Claim 11 recites "a recombinant DNA construct according to claim 10, wherein said promoter region comprises the nucleotide sequence of SEQ. ID. NO. 1." The examiner asserted that the paragraphs previously cited by Appellants do not support recited limitations in claim 11.

Claim 11 recites that the promoter region "comprises the nucleotide sequence of SEQ. ID. NO. 1." The specification specifically teaches the sequence of SEQ. ID. NO. 1, in Figure 1. Further, the specification specifically identifies that the sequence set forth in Figure 1 represents the promoter region of the GLP-2R gene. Specification, paragraphs 17 and 43.

Therefore, the claim amendment to claim 11 does not introduce new matter under 35 U.S.C. § 132. Accordingly, this rejection should be reversed.

## CONCLUSION

For at least the foregoing, the Board of Patent Appeals and Interferences should reverse the § 112 first and second paragraph rejections of claim 1-5, 9, 10 and 11.

**Appendix A** contains a clean copy of the claims on appeal.

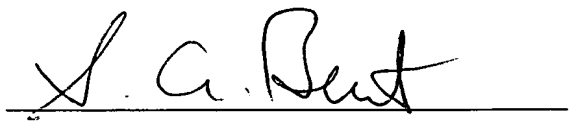
**Appendix B** contains a marked-up copy of the claims amended as proposed in the Amendment submitted concurrently herewith..

**Appendix C** contains a clean copy of the claims amended as proposed in the Amendment submitted concurrently herewith..

**Appendix D** contains a copy of the U.S. Patent Office Written Description Guidelines, 66 Fed. Reg. 1099-1107.

The Patent Office is invited to contact the undersigned attorney of record at the telephone number set forth below if it is believed that a telephone conference might be useful in expediting prosecution or resolving any or all of the issues on appeal.

Respectfully submitted,



Date April 30, 2004

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## APPENDIX A

## CLEAN COPY OF PENDING CLAIMS

1. A recombinant DNA construct, comprising a promoter region of a GLP-2 receptor gene and linked for expression therewith, a heterologous gene of interest, wherein the promoter region comprises at least the last 1,000 nucleotides of (A) the murine nucleotide sequence of SEQ ID NO. 1 or (B) a mammalian homolog of said murine nucleotide sequence.

2. A recombinant DNA construct according to claim 1, wherein the promoter region is selected from the promoter region of the mouse GLP-2 receptor gene, the promoter region of a homolog of the mouse GLP-2 receptor gene, or a variant of such promoter regions that incorporates a truncation, insertion, deletion, or addition and retains the function of a GLP-2 receptor gene promoter region.

3. A recombinant DNA construct according to claim 1, wherein the heterologous gene of interest is a reporter gene.

4. A recombinant DNA construct according to claim 1, wherein the heterologous gene of interest encodes a therapeutic protein.

5. A cell incorporating a recombinant DNA construct as defined in claim 1.

9. A recombinant DNA construct according to claim 1, wherein said promoter region is a mammalian homolog which is a human homolog comprising at least residues –1 to –203 illustrated in Figure 7b (bases 1-201 of SEQ ID NO:7).

10. A recombinant DNA construct according to claim 1, wherein the promoter region comprises from 1.5 kb to 10.6 kb of the murine GLP-2 receptor promoter.

11. A recombinant DNA construct according to claim 10, wherein said promoter region comprises the nucleotide sequence of SEQ. ID. NO. 1.

## APPENDIX B

## MARKED COPY OF PROPOSED AMENDED CLAIMS

1. (Currently Amended) A recombinant DNA construct, comprising a promoter region of a GLP-2 receptor gene and linked for expression therewith, a heterologous gene of interest, wherein the promoter region comprises at least the last 1,000 nucleotides upstream of the transcription start site of (A) the murine nucleotide sequence of SEQ ID NO. 1 or (B) a mammalian homolog of said murine nucleotide sequence.

2. (Original) A recombinant DNA construct according to claim 1, wherein the promoter region is selected from the promoter region of the mouse GLP-2 receptor gene, the promoter region of a homolog of the mouse GLP-2 receptor gene, or a variant of such promoter regions that incorporates a truncation, insertion, deletion, or addition and retains the function of a GLP-2 receptor gene promoter region.

3. (Original) A recombinant DNA construct according to claim 1, wherein the heterologous gene of interest is a reporter gene.

4. (Original) A recombinant DNA construct according to claim 1, wherein the heterologous gene of interest encodes a therapeutic protein.

5. (Original) A cell incorporating a recombinant DNA construct as defined in claim 1.

9. (Previously presented) A recombinant DNA construct according to claim 1, wherein said promoter region is a mammalian homolog which is a human homolog comprising at least residues –1 to –203 illustrated in Figure 7b (bases 1-201 of SEQ ID NO:7).

10. (Previously presented) A recombinant DNA construct according to claim 1, wherein the promoter region comprises from 1.5 kb to 10.6 kb of the murine GLP-2 receptor promoter.

11. (Previously presented) A recombinant DNA construct according to claim 10, wherein said promoter region comprises the nucleotide sequence of SEQ. ID. NO. 1.

## APPENDIX C

## CLEAN COPY OF PROPOSED AMENDED CLAIMS

1. (Currently Amended) A recombinant DNA construct, comprising a promoter region of a GLP-2 receptor gene and linked for expression therewith, a heterologous gene of interest, wherein the promoter region comprises at least the last 1,000 nucleotides upstream of the transcription start site of (A) the murine nucleotide sequence of SEQ ID NO. 1 or (B) a mammalian homolog of said murine nucleotide sequence.

2. (Original) A recombinant DNA construct according to claim 1, wherein the promoter region is selected from the promoter region of the mouse GLP-2 receptor gene, the promoter region of a homolog of the mouse GLP-2 receptor gene, or a variant of such promoter regions that incorporates a truncation, insertion, deletion, or addition and retains the function of a GLP-2 receptor gene promoter region.

3. (Original) A recombinant DNA construct according to claim 1, wherein the heterologous gene of interest is a reporter gene.

4. (Original) A recombinant DNA construct according to claim 1, wherein the heterologous gene of interest encodes a therapeutic protein.

5. (Original) A cell incorporating a recombinant DNA construct as defined in claim 1.

9. (Previously presented) A recombinant DNA construct according to claim 1, wherein said promoter region is a mammalian homolog which is a human homolog comprising at least residues –1 to –203 illustrated in Figure 7b (bases 1-201 of SEQ ID NO:7).

10. (Previously presented) A recombinant DNA construct according to claim 1, wherein the promoter region comprises from 1.5 kb to 10.6 kb of the murine GLP-2 receptor promoter.

11. (Previously presented) A recombinant DNA construct according to claim 10, wherein said promoter region comprises the nucleotide sequence of SEQ. ID. NO. 1.

**APPENDIX D**

**U.S. PATENT OFFICE WRITTEN DESCRIPTION GUIDELINES**

**66 FED.REG. 1099-1107**

an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

Dated: December 29, 2000.

**Q. Todd Dickinson,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 01-322 Filed 1-4-01; 8:45 am]

BILLING CODE 3510-16-U

## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

**[Docket No. 991027288-0264-02]**

**RIN 0651-AB10**

### Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice.

**SUMMARY:** These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. These Guidelines supersede the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" that were published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.

**DATES:** The Guidelines are effective as of January 5, 2001.

**FOR FURTHER INFORMATION CONTACT:** Stephen Walsh by telephone at (703) 305-9035, by facsimile at (703) 305-9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at "stephen.walsh@uspto.gov"; or Linda Therkorn by telephone at (703) 305-8800, by facsimile at (703) 305-8825, by mail addressed to Box Comments, Commissioner for Patents, Washington, DC 20231, or by electronic mail at "linda.therkorn@uspto.gov."

**SUPPLEMENTARY INFORMATION:** As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

#### Discussion of Public Comments

Comments were received from 48 individuals and 18 organizations in response to the request for comments on the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. The written comments have been carefully considered.

#### Overview of Comments

The majority of comments favored issuance of final written description guidelines with minor revisions. Comments pertaining to the written description guidelines are addressed in detail below. A few comments addressed particular concerns with respect to the associated examiner training materials that are available for public inspection at the USPTO web site (www.uspto.gov). Such comments will be taken under advisement in the revision of the training materials; consequently, these comments are not specifically addressed below as they do not impact the content of the Guidelines. Several comments raised issues pertaining to the patentability of ESTs, genes, or genomic inventions with respect to subject matter eligibility (35 U.S.C. 101), novelty (35 U.S.C. 102), or obviousness (35 U.S.C. 103). As these comments do not pertain to the written description requirement under 35 U.S.C. 112, they have not been addressed. However, the aforementioned comments are fully addressed in the "Discussion of Public Comments" in the "Utility Examination Guidelines" Final Notice, which will be published at or about the same time as the present Guidelines.

#### Responses to Specific Comments

(1) *Comment:* One comment stated that the Guidelines instruct the patent examiner to determine the correspondence between what applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed, and that such analysis will lead to error. According to the comment, the examiner may decide what applicant should have claimed and reject the claim for failure to claim what the examiner considers to be the invention. Another comment suggested that the Guidelines should clarify what is meant by "essential features of the invention." Another comment suggested that what applicant has identified as the "essential distinguishing characteristics" of the invention should be understood in terms of *Fiers* v. *Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) ("Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name,

formula, or definitive chemical or physical properties.").

*Response:* The suggestions have been adopted in part. The purpose of the written description analysis is to confirm that applicant had possession of what is claimed. The Guidelines have been modified to instruct the examiners to compare the scope of the invention claimed with the scope of what applicant has defined in the description of the invention. That is, the Guidelines instruct the examiner to look for consistency between a claim and what provides adequate factual support for the claim as judged by one of ordinary skill in the art from reading the corresponding written description.

(2) *Comment:* Two comments urge that *Regents of the University of California* v. *Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), is bad law and should not be followed by the USPTO because it conflicts with binding precedent, such as *Vas-Cath* v. *Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). *Response:* The final Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit. *Eli Lilly* is a precedential decision by the Court that has exclusive jurisdiction over appeals involving patent law. Accordingly, the USPTO must follow *Eli Lilly*. Furthermore, the USPTO does not view *Eli Lilly* as conflicting with *Vas-Cath*. *Vas-Cath* explains that the purpose of the written description requirement is to ensure that the applicant has conveyed to those of skill in the art that he or she was in possession of the claimed invention at the time of filing. *Vas-Cath*, 935 F.2d at 1563–64, 19 USPQ2d at 1117. *Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed.

(3) *Comment:* Several comments urged that the Guidelines do not recognize the inconsistency between the original claim doctrine and the written description requirement as set out in *Fiers* and *Eli Lilly*. On the other hand, another comment asserts that there is no strong presumption that an originally filed claim constitutes an adequate written description of the claimed subject matter. Several comments indicate that *in haec verba* support should be sufficient to comply with the written description requirement. Two comments urge that the concept of constructive reduction to practice upon filing of an application has been ignored. *Response:* As noted above, the USPTO does not find *Fiers* and *Eli Lilly* to be in conflict with binding precedent. An original claim may provide written description for itself, but it still must be an *adequate* written description which establishes that the inventor was in possession of the invention. The "original claim doctrine" is founded on cases which stand for the proposition that originally filed claims are part of the written description of an application as filed, and thus subject matter which is present only in originally filed claims need not find independent support in the specification. *See, e.g., In re Koller*, 613 F.2d 819, 824, 204 USPQ 702, 706 (CCPA 1980) (later added claims of similar scope and wording were adequately described by original claims); *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149, 149 (CCPA 1973) ("Under these circumstances, we consider the original claim in itself adequate 'written description' of the claimed invention. It was equally a 'written description' * * * whether located among the original claims or in the descriptive part of the specification."). However, as noted in the preceding comment, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed. When the name of a novel chemical compound does not convey sufficient structural information about the compound to identify the compound, merely reciting the name is not enough to show that the inventor had possession of the compound at the time the name was written. The Guidelines indicate that there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed, consistent with *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). In most cases, the statement that "an originally filed claim is its own written description," is borne out because the claim language conveys to others of skill in the art that the applicant was "in possession" of what is claimed. The Guidelines emphasize that the burden of proof is on the examiner to establish that a description as filed is not adequate and require the examiner to introduce sufficient evidence or technical reasoning to shift the burden of going forward with contrary evidence to the applicant.

(4) *Comment:* One comment stated that the Guidelines change the substance of the written description requirement to require some level of enablement. The comment stated that the *Eli Lilly* case should not be followed because its change in the quality of the description required is in conflict with precedent. Another comment suggested that to comply with the written description requirement, the description must both (i) demonstrate possession of the claimed invention by the applicant; and (ii) put the public in possession of the claimed invention. *Response:* As noted in the comment above, the USPTO is bound by the Federal Circuit's decision in *Eli Lilly*. The Guidelines have been revised to clarify that an applicant must provide a description of the claimed invention which shows that applicant was in possession of the claimed invention. The suggestion to emphasize that the written description requirement must put the public in possession of the invention has not been adopted because it removes much of the distinction between the written description requirement and the enablement requirement. Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.

(5) *Comment:* One comment suggested that the Guidelines should provide examples of situations in which the written description requirement was met but the enablement requirement was not, and vice versa. Another comment stated that examiners often use enablement language in making

written description rejections. *Response:* The enablement and written description requirements are not coextensive and, therefore, situations will arise in which one requirement is met but the other is not. Federal Circuit case law demonstrates many circumstances where enablement or written description issues, but not both, were before the Court. These Guidelines are intended to clarify for the examining corps the criteria needed to satisfy the written description requirement. For examples applying these Guidelines to hypothetical fact situations, see the "Synopsis of Application of Written Description Guidelines" (examiner training materials available on-line at *http://www.uspto.gov/web/menu/written.pdf).* These examples, as well as the examination form paragraphs and instructions on their proper use, provide the appropriate language examiners should use in making written description rejections.

(6) *Comment:* One comment disagreed with the statement in an endnote that "the fact that a great deal more than just a process is necessary to render a product invention obvious means that a great deal more than just a process is necessary to provide written description for a product invention." The comment indicated that the statement is overly broad and inconsistent with the "strong presumption that an adequate written description of the claimed invention is present when the application is filed." As an extreme case, for example, for product-by-process claims, nothing else would be needed to provide the written description of the product. *Response:* The endnote has been clarified and is now more narrowly drawn. However, there is no *per se* rule that disclosure of a process is sufficient to adequately describe the products produced by the process. In fact, *Fiers* v. *Revel* and *Eli Lilly* involved special circumstances where the disclosure of a process of making and the function of the product alone did not provide an adequate written description for product claims. Even when a product is claimed in a product-by-process format, the adequacy of the written description of the process to support product claims must be evaluated on a case-by-case basis.

(7) *Comment:* Several comments urge that actual reduction to practice, as a method of satisfying the written description requirement by demonstrating possession, has been over-emphasized. *Response:* The Guidelines have been clarified to state that describing an actual reduction to practice is one of a number of ways to show possession of the invention. Description of an actual reduction to practice offers an important "safe haven" that applies to all applications and is just one of several ways by which an applicant may demonstrate possession of the claimed invention. Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others. Thus, the emphasis on actual reduction to practice is appropriate in those cases where the inventor cannot provide an adequate description of what the composition is, and a definition by function is insufficient to define a composition "because it is only an indication of what the [composition] does, rather than what it is." *Eli Lilly,* 119 F.3d at 1568, 43 USPQ at 1406. *See also Amgen Inc.* v. *Chugai Pharmaceutical Co.,* 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

(8) *Comment:* One comment asserts that the citation to *Pfaff* v. *Wells Electronics, Inc.,* 525 U.S. 55, 48 USPQ2d 1641 (1998) is inappropriate and should be deleted because *Pfaff* is concerned with § 102(b) on-sale bar, not written description. Another comment suggested that the Guidelines should provide an explanation of how the "ready for patenting" concept of *Pfaff* should be used in determining compliance with the written description requirement. *Response:* The Guidelines state the general principle that actual reduction to practice is not required to show possession of, or to adequately describe, a claimed invention (although, as noted in the previous comment, an actual reduction to practice is crucial in relatively rare instances). An alternative is to show that the invention described was "ready for patenting" as set out in *Pfaff.* For example, a *description* of activities that demonstrates the invention was "ready for patenting" satisfies the written description requirement. As *Wertheim* indicates, "how the specification accomplishes this is not material." 541 F.2d at 262, 191 USPQ at 96.

(9) *Comment:* One comment stated that the written description of a claimed DNA should be required to include the complete sequence of the DNA and claims should be limited to the DNA sequence disclosed. *Response:* Describing the complete chemical structure, *i.e.,* the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. *See Eli Lilly,* 119 F.3d at 1566, 43 USPQ2d at 1404 ("An adequate written description of a DNA * * * requires a precise definition, *such as* by structure, formula, chemical name, or physical properties." (emphasis added, internal quote omitted)). Therefore, there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.

(10) *Comment:* One comment stated that it is difficult to envision how one could provide a description of sufficient identifying characteristics of the invention without physical possession of a species of the invention, and thus this manner of showing possession should be considered as a way to show actual reduction to practice. *Response:* This suggestion has not been adopted. The three ways of demonstrating possession as set forth in the Guidelines are merely exemplary and are not mutually exclusive. While there are some cases where a description of sufficient relevant identifying characteristics will evidence an actual reduction to practice, there are other cases where it will not. *See, e.g., Ralston Purina Co.* v. *Far-Mar-Co, Inc.,* 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed. Cir. 1985) (disclosure taken with the knowledge of those skilled in the art may be sufficient support for claims).

(11) *Comment:* One comment stated that the Guidelines should be revised to indicate that the test of disclosure of sufficiently detailed drawings should be expanded to include structural claiming of chemical entities. *Response:* The suggestion has been adopted.

(12) *Comment:* One comment stated that the Guidelines should reflect that an inventor is in possession of the invention when the inventor demonstrably has at least a complete conception thereof, and that factors and attributes which provide proof of written description should include evidence typically provided to prove a complete conception. *Response:* The suggestion has not been adopted because the conception analysis typically involves documentary evidence in addition to the description of the invention in the application as filed. However, it is acknowledged that if evidence typically provided to prove a complete conception is present in the specification as filed, it would be sufficient to show possession. The Federal Circuit has stated "[t]he conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession

of the complete mental picture of the invention." *Burroughs Wellcome Co.* v. *Barr Labs., Inc.*, 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). As further noted by the Federal Circuit, in order to prove conception, "a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged conception." *Coleman* v. *Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985).

(13) *Comment:* One comment indicated that a "possession" test does not appear in Title 35 of the U.S. Code and is not clearly stated by the Federal Circuit. Therefore, it is recommended that patent examiners be directed to use existing judicial precedent to make rejections of claims unsupported by a statutory written description requirement. *Response:* While the Federal Circuit has not specifically laid out a "possession" test, the Court has clearly indicated that possession is a cornerstone of the written description inquiry. *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *see also Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) ("[o]ne skilled in the art, reading the disclosure, must immediately discern the limitation at issue in the claims") (internal quote omitted). The possession test as set forth in the Guidelines is extrapolated from case law in a wide variety of technologies and is not intended to be limiting. Any rejections made by examiners will be made under 35 U.S.C. 112, ¶1, with supporting rationale. Final rejections are appealable if applicant disagrees and follows the required procedures to appeal.

(14) *Comment:* Two comments indicated that if the amino acid sequence for a polypeptide whose utility has been identified is described, then the question of possession of a class of nucleotides encoding that polypeptide can be addressed as a relatively routine matter using the understanding of the genetic code, and that the endnote addressing this issue should be revised. *Response:* The suggestion of these comments has been incorporated in the Guidelines and will be reflected in the training materials. However, based upon *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), this does not mean that applicant was in possession of any particular species of the broad genus.

(15) *Comment:* One comment disagreed with an endnote which stated that a laundry list disclosure of moieties does not constitute a written description of every species in a genus. Specifically, the comment indicates that if the existence of a functional genus is adequately described in the specification, a laundry list of the species within that genus must satisfy the written description requirement. *Response:* The suggestion to revise the endnote will not be adopted. A lack of adequate written description problem arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosure. This was aptly demonstrated in *In re Bell* and *In re Baird* where possession of a large genus did not put a person of ordinary skill in the art in possession of any particular species. *See also Purdue Pharma*, 230 F.3d at 1328, 56 USPQ2d at 1487 (because the original specification did not disclose the later claimed concentration ratio was a part of the invention, the inventors cannot argue that they are merely narrowing a broad invention).

(16) *Comment:* One comment suggested that in the majority of cases, a single species will support a generic claim, and that the Guidelines should emphasize this point. *Response:* The suggestion has been adopted to a limited degree. The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus. Note, however, *Tronzo* v. *Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998), where the species in the parent application was held not to provide written description support for the genus in the child application.

(17) *Comment:* One comment asserted that the Guidelines should focus on the compliance of the claims, not the specification, with the written description requirement. *Response:* This suggestion will not be adopted. "The specification shall contain a written description of the invention." 35 U.S.C. 112. The claims are part of the specification. *Id.*, ¶ 2. If an adequate description is provided, it will suffice "whether located among the original claims or in the descriptive part of the specification." *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149 (CCPA 1973). The entire disclosure, including the specification, drawings, and claims, must be considered.

(18) *Comment:* One comment asserted that the Guidelines confuse "new matter," 35 U.S.C. 132, with the written description requirement, and that the same standard for written description should be applied to both original claims and new or amended claims. *Response:* The Guidelines indicate that for both original and amended claims, the inquiry is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed.

(19) *Comment:* One comment suggested that the second paragraph of the section pertaining to determining what the claim as a whole covers should be deleted because it relates more to compliance with § 112, second paragraph, than with the written description requirement. *Response:* This suggestion will not be adopted. The claims must be construed and all issues as to the scope and meaning of the claim must be explored during the inquiry into whether the written description requirement has been met. The concept of treating the claim as a whole is applicable to all criteria for patentability.

(20) *Comment:* One comment suggested a different order for the general analysis for determining compliance with the written description requirement, starting with reading the claim, then the specification, and then determining whether the disclosure demonstrates possession by the applicant. *Response:* This suggestion will not be adopted. The claims must be construed as broadly as reasonable in light of the specification and the knowledge in the art. *See In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Then the disclosure must be evaluated to determine whether it adequately describes the claimed invention, i.e., whether it conveys to a person having ordinary skill in the art that the applicant had possession of what he or she now claims.

(21) *Comment:* Several comments suggested that the Guidelines are unclear with regard to how the examiner should treat the transitional phrase "consisting essentially of." The comments also suggested that the endnote that explains "consisting essentially of" does not make clear how the use of this intermediate transitional language affects the scope of the claim. Several comments stated that the USPTO does not have legal authority to treat claims reciting this language as open (equivalent to "comprising"). Another comment suggested that the phrase "clear indication in the specification" be replaced with "explicit or implicit indication." *Response:* The transitional phrase "consisting essentially of" "excludes

ingredients that would 'materially affect the basic and novel characteristics' of the claimed composition." *Atlas Powder Co.* v. *E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984). The basic and novel characteristics of the claimed invention are limited by the balance of the claim. *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). However, during prosecution claims must be read broadly, consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Thus, *for purposes of searching for and applying prior art in a rejection under 35 U.S.C. 102 or 103*, if the specification or the claims do not define the "basic and novel" properties of the claimed subject matter (or if such properties are in dispute), the broadest reasonable interpretation consistent with the specification is that the basic and novel characteristics are merely the presence of the recited limitations. *See, e.g., Janakirama-Rao*, 317 F.2d at 954, 137 USPQ at 895–96. This does not indicate that the intermediate transitional language is never given weight. Applicants may amend the claims to avoid the rejections or seek to establish that the specification provides definitions of terms in the claims that define the basic and novel characteristics of the claimed invention which distinguish the claimed invention from the prior art. When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). The language used in the Guidelines is consistent with *PPG Industries Inc.* v. *Guardian Industries Corp.*, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics.").

(22) *Comment:* One comment stated that the written description should "disclose the invention," including why the invention works and how it was developed. *Response:* This suggestion has not been adopted. An inventor does not need to know how or why the invention works in order to obtain a patent. *Newman* v. *Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). To satisfy the enablement requirement of 35 U.S.C. 112, ¶1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶ 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. There is no statutory basis to require disclosure of why an invention works or how it was developed. "Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. 103(a).

(23) *Comment:* One comment recommended that the phrases "emerging and unpredictable technologies" and "unpredictable art" be replaced with the phrase—inventions characterized by factors which are not reasonably predictable in terms of the ordinary skill in the art—. *Response:* The suggestion is adopted in part and the recommended phrase has been added as an alternative.

(24) *Comment:* One comment recommended that the phrase "conventional in the art" be replaced with—part of the knowledge of one of ordinary skill in the art—. *Response:* The suggestion is adopted in part and the recommended phrase has been added as an alternative. The standard of "conventional in the art" is supported by case law holding that a patent specification "need not teach, and preferably omits, what is well known in the art." *See Spectra-Physics, Inc.* v. *Coherent, Inc.*, 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). *See also Atmel Corp.* v. *Information Storage Devices, Inc.*, 198 F.3d 1374, 1382, 53 USPQ2d 1225, 1231 (Fed. Cir. 1999).

(25) *Comment:* One comment recommended that the Guidelines be amended to state that the appropriate skill level for determining possession of the claimed invention is that of a person of *ordinary* skill in the art. *Response:* The comment has not been adopted. The statutory language itself indicates that compliance with the requirements of 35 U.S.C. 112, ¶1, is judged from the standard of "any person skilled in the art." It is noted, however, that the phrases "one of skill in the art" and "one of ordinary skill in the art" appear to be synonymous. *See, e.g., Union Oil Co.* v. *Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow *persons of ordinary skill in the art* to recognize that [he or she] invented what is claimed.' Thus, § 112, ¶ 1, ensures that, as of the filing date, the inventor conveyed with reasonable clarity to *those of skill in the art* that he was in possession of the subject matter of the claims." (citations omitted, emphasis added)).

(26) *Comment:* One comment stated that an endnote misstates the relevant law in stating that, to show inherent written descriptive support for a claim limitation, the inherent disclosure must be such as would be recognized by a person of ordinary skill in the art. The comment recommended that the endnote be amended to delete the reference to recognition by persons of ordinary skill and to cite *Pingree* v. *Hull*, 518 F.2d 624, 186 USPQ 248 (CCPA 1975), rather than *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). *Response:* The comment has not been adopted. Federal Circuit precedent makes clear that an inherent disclosure must be recognized by those of ordinary skill in the art. *See, e.g., Hyatt* v. *Boone*, 146 F.3d 1348, 1354–55, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998) ("[T]he purpose of the description requirement is 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.' * * * Thus, the written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided *and would have been so understood* at the time the patent application was filed." (emphasis added)). *See also Reiffin* v. *Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000) (The "application considered as a whole must convey to one of ordinary skill in the art, either explicitly or inherently, that [the inventor] invented the subject matter claimed * * *. See * * * *Continental Can Co. USA* v. *Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (descriptive matter may be inherently present in a specification if one skilled in the art would necessarily recognize such a disclosure)").

(27) *Comment:* Several comments pointed out an inconsistency in the **Federal Register** Notice re: the Revised Interim Written Description Guidelines. The inconsistency concerned the treatment of claims directed to an isolated DNA comprising SEQ ID NO:1 wherein SEQ ID NO:1 is an expressed sequence tag. The comments contrasted paragraphs 34 and 35 of the Response to

Public Comments with the statement in the text of the Guidelines that a genus must be supported by a representative number of species (as analyzed in Example 7 of the training materials). *Response:* The USPTO acknowledges that there was an inconsistency. The Office notes that a claim reciting a nucleic acid comprising SEQ ID NO:1 may be subject to a rejection for lack of an adequate written description where particular identifiable species within the scope of the claim lack an adequate written description. The training materials as amended exemplify an appropriate analysis.

(28) *Comment:* One comment stated that the USPTO should respond to the issue of whether the U.S. is meeting its TRIPs obligations. This comment noted that the USPTO did not address an earlier comment regarding the "Interim Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement," 63 FR 32,639, June 15, 1998, which questioned whether the written description requirement is truly different from the enablement requirement, and indicated that such a requirement may be contrary to the TRIPs provisions of the World Trade Organization (Article 27.1). Article 27.1 requires WTO Members to, *inter alia*, make patents available, with limited exceptions, for products and processes in all fields of technology so long as those products and processes are new, involve an inventive step, and are capable of industrial application. The comment further suggested a response. *Response:* TRIPs Article 27 does not address what must be included in a patent application to allow WTO Member officials to determine whether particular inventions meet the standards for patentability established in that Article. TRIPs Article 29, which is more relevant to this comment, states that Members "shall require" patent applicants to disclose their invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." If the written description is not clear and complete, the applicant may not have been in possession of the invention. This may support both written description and enablement standards. In addition, Article 29 expressly authorizes Members to require patent applicants to disclose the best method the inventor knows at the time of filing an application for carrying out the invention.

(29) *Comment:* Two comments commended the USPTO for eliminating the Biotechnology Specific Examples in the Revised Interim Written Description Guidelines and providing separate training materials. One comment indicated a need to reconfirm the examples set forth in the Interim Written Description Guidelines published in 1998. *Response:* The current training materials reflect the manner in which the USPTO interprets the Written Description Guidelines.

(30) *Comment:* Several comments addressed specific concerns about the examiner training materials. *Response:* The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials in view of the revisions to the Guidelines. The specific comments will not be addressed herein as they do not impact the language of the Guidelines.

**Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement**

These "Written Description Guidelines" are intended to assist Office personnel in the examination of patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶ 1. This revision is based on the Office's current understanding of the law and public comments received in response to the USPTO's previous request for public comments on its Revised Interim Written Description Guidelines and is believed to be fully consistent with binding precedent of the U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts.

This revision does not constitute substantive rulemaking and hence does not have the force and effect of law. It is designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

These Guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a *prima facie* case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. 101, 102, 103, and 112, is to be conducted prior to completing an Office action which includes a rejection for lack of written description. Office personnel are to rely on this revision of the Guidelines in the event of any inconsistent treatment of issues involving the written description requirement between these Guidelines and any earlier guidance provided from the Office.

**I. General Principles Governing Compliance With the "Written Description" Requirement for Applications**

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement.[1] The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed."[2] Another objective is to put the public in possession of what the applicant claims as the invention.[3] The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.[4] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[5] Possession may be shown in a variety of ways including description of an actual reduction to practice,[6] or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete,[7] or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[8] A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c).[9] Compliance with the written description requirement is a question of

fact which must be resolved on a case-by-case basis.[10]

*A. Original Claims*

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.[11] However, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.[12] The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.[13] This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.[14] A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.[15]

*B. New or Amended Claims*

The proscription against the introduction of new matter in a patent application[16] serves to prevent an applicant from adding information that goes beyond the subject matter originally filed.[17] Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement.[18] While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.[19] Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed.[20]

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention.[21] A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement.[22]

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.[23]

**II. Methodology for Determining Adequacy of Written Description**

*A. Read and Analyze the Specification for Compliance With 35 U.S.C. 112, ¶1*

Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶ 1. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed;[24] however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.[25] Consequently, rejection of an original claim for lack of written description should be rare. The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis.[26]

1. For Each Claim, Determine What the Claim as a Whole Covers

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.[27] The entire claim must be considered, including the preamble language[28] and the transitional phrase.[29] The claim as a whole, including all limitations found in the preamble,[30] the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement.[31]

The examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble.[32] The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, ¶ 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

2. Review the Entire Application to Understand How Applicant Provides Support for the Claimed Invention Including Each Element and/or Step

Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention.[33] The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed[34] and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.[35]

3. Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention as a Whole at the Time the Application Was Filed

a. Original claims. Possession may be shown in many ways. For example, possession may be shown, *inter alia*, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.[36]

A specification may describe an actual reduction to practice by showing

that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.[37] Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 *et seq.*[38]

An applicant may show possession of an invention by disclosure of drawings[39] or structural chemical formulas[40] that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional.[41] This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics[42] which provide evidence that applicant was in possession of the claimed invention,[43] *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[44] What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.[45] If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.[46]

(1) For each claim drawn to a single embodiment or species:[47]

(a) Determine whether the application describes an actual reduction to practice of the claimed invention.

(b) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

(c) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.

(i) Determine whether the application as filed describes the complete structure (or acts of a process) of the claimed invention as a whole. The complete structure of a species or embodiment typically satisfies the requirement that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention.[48] If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. 112, ¶ 1, for lack of written description must not be made.

(ii) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.[49]

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.[50] Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention.[51] In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim.[52] Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention.[53]

Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

(2) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above).[54]

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus.[55] What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus.[56] Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.[57] If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

b. New claims, amended claims, or claims asserting entitlement to the benefit of an earlier priority date or filing date under 35 U.S.C. 119, 120, or

365(c). The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims.[58] However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims.[59] To comply with the written description requirement of 35 U.S.C. 112, ¶ 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly,[60] implicitly,[61] or inherently[62] supported in the originally filed disclosure.[63] Furthermore, each claim must include all elements which applicant has described as essential.[64]

If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, ¶ 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

**III. Complete Patentability Determination Under All Statutory Requirements and Clearly Communicate Findings, Conclusions, and Their Bases**

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112, ¶ 1, is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of title 35 of the U.S. Code.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

*A. For Each Claim Lacking Written Description Support, Reject the Claim Under Section 112, ¶ 1, for Lack of Adequate Written Description*

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.[65] The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.[66] In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(1) Identify the claim limitation at issue; and

(2) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description.[67]

*B. Upon Reply by Applicant, Again Determine the Patentability of the Claimed Invention, Including Whether the Written Description Requirement Is Satisfied by Reperforming the Analysis Described Above in View of the Whole Record*

Upon reply by applicant, before repeating any rejection under 35 U.S.C. 112, ¶ 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do *not* repeat the rejection in the next Office action. If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. 112, ¶ 1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. When a rejection is maintained, any affidavits relevant to the 112, ¶ 1, written description requirement,[68] must be thoroughly analyzed and discussed in the next Office action.

Dated: December 29, 2000.

**Q. Todd Dickinson,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

**Endnotes**

[1] *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).

[2] *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).

[3] *See Regents of the University of California* v. *Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998).

[4] *See, e.g., Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, *i.e.*, whether that party can "make the claim" corresponding to the interference count. *See, e.g., Martin* v. *Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987).

In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. *See In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); *accord In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (accord). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, *i.e.*, how much description is enough.

[5] *Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

[6] An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 *et seq. See also Deposit of Biological Materials for Patent Purposes, Final Rule*, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." *Id.* at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the

patent issues, the description must be sufficient to aid in the resolution of questions of infringement." *Id.* at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. *See, e.g., In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). *See also* 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

[7] *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[8] *See Amgen, Inc.* v. *Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

[9] A description requirement issue can arise for original claims (*see, e.g., Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398) as well as new or amended claims. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (*see, e.g., In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (*see, e.g., Tronzo* v. *Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *Fiers* v. *Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (*see, e.g., Fields* v. *Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)).

[10] *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

[11] *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims").

[12] See endnote 4.

[13] For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (*e.g.*, promoters, enhancers, coding regions, and other regulatory elements) which are also included.

[14] A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *Cf. In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405.

*Compare Fonar Corp.* v. *General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) ("As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. * * * Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software.").

[15] *See, e.g., Fujikawa* v. *Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("*If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original); *Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors * * * considered the [] ratio to be part of their invention * * *. There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

[16] 35 U.S.C. §§ 132 and 251. *See also In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). *See* Manual of Patent Examining Procedure (MPEP) §§ 2163.06–2163.07 (7th Ed., Rev. 1, Feb. 2000) for a more detailed discussion of the written description requirement and its relationship to new matter.

[17] The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

[18] *See, e.g., In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

[19] *In re Oda*, 443 F.2d 1200, 170 USPQ 260 (CCPA 1971). With respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. *See, e.g.*, Peter Richterich, *Estimation of Errors in 'Raw' DNA Sequences: A Validation Study*, 8 Genome Research 251–59 (1998). If an application as filed includes sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR § 1.801 *et seq.*, amendment may be permissible.

[20] Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error. Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR § 1.804 stating that the biological material which is deposited is a biological material specifically defined in the application as filed.

[21] *See, e.g., Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, *inter alia*, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means.); *Johnson Worldwide Associates* v. *Zebco Corp.*, 175 F.3d 985, 993, 50 USPQ2d 1607, 1613 (Fed. Cir. 1999) (In *Gentry Gallery*, the "court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element—the 'control means'—as 'the only possible location' and that variations were 'outside the stated purpose of the invention.' *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. *Gentry Gallery*, then, considers the situation where the patent's disclosure makes crystal clear that a particular (*i.e.*, narrow) understanding of a claim term is an 'essential element of [the inventor's] invention.' "); *Tronzo* v. *Biomet*, 156 F.3d at 1158–59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed "conical cup" in view of the disclosure of the

parent application stating the advantages and importance of the conical shape.).

[22] *See Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) ("[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only *certain aryl radicals* and certain specifically substituted aryl radicals [*i.e.*, aryl azides] would be suitable for such purposes.") (emphasis in original). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. 112, ¶ 1, as not enabling, or under 35 U.S.C. 112, ¶ 2. *See In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). *See also* MPEP § 2172.01.

[23] *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563–64, 19 USPQ2d at 1117.

[24] *Wertheim*, 541 F.2d at 262, 191 USPQ at 96.

[25] *See* MPEP §§ 714.02 and 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure."); and MPEP § 2163.04 ("If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.").

[26] *See In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close [to the claimed invention] the description must come to comply with § 112 must be left to case-by-case development."); *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure).

[27] *See, e.g., In re Morris*, 127 F.3d 1048, 1053–54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

[28] "Preamble language" is that language in a claim appearing before the transitional phase, *e.g.*, before "comprising," "consisting essentially of," or "consisting of."

[29] The transitional term "comprising" (and other comparable terms, *e.g.*, "containing," "including," and "having") is "open-ended—it covers the expressly recited subject matter, alone or in combination with unrecited subject matter. *See, e.g., Genentech, Inc.* v. *Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (" 'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves the "claim open for the inclusion of unspecified ingredients even in major amounts"). "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries* v. *Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353–54 (Fed. Cir. 1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to "comprising." *See, e.g., PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). *See also In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895–96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

[30] *See Pac-Tec Inc.* v. *Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention).

[31] An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

[32] *See, e.g., Bell Communications Research, Inc.* v. *Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) ("[A] claim preamble has the import that the claim as a whole suggests for it."); *Corning Glass Works* v. *Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim.").

[33] An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. *Compare Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327 ("one skilled in the art who read Rasmussen's specification would understand that it is unimportant *how* the layers are adhered, so long as they are adhered") (emphasis in original), *with Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it").

[34] *See, e.g., Wang Labs.* v. *Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

[35] *See, e.g., Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379–80, 231 USPQ 81, 90 (Fed. Cir. 1986).

[36] *See, e.g., Purdue Pharma L.P.* v. *Faulding Inc.*, 230 F.3d 1320, ___, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); *see also Pfaff* v. *Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 ("The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the *Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.").

[37] *Cooper* v. *Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). *See also UMC Elecs. Co.* v. *United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) ("[T]here cannot be a reduction to practice of the invention * * * without a physical embodiment which includes all limitations of the claim."); *Estee Lauder Inc.* v. *L'Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."); *Mahurkar* v. *C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves).

[38] 37 CFR 1.804, 1.809. *See also* endnote 6.

[39] *See, e.g., Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 ("drawings alone may provide a 'written description' of an invention as required by § 112"); *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America* v. *United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification.").

[40] *See, e.g., Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.").

[41] *See Hybritech* v. *Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp.* v. *General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required).

[42] For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine when the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme map. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its expression to produce the protein of interest is strong evidence of possession of an mRNA for the protein.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. *See Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966 ("written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention").

[43] A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. *See also Fiers*, 984 F.2d at 1169–71, 25 USPQ2d at 1605–06 (discussing *Amgen Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

[44] If a claim limitation invokes 35 U.S.C. 112, ¶ 6, it must be interpreted to cover the corresponding structure, materials, or acts in the specification and "equivalents thereof." *See* 35 U.S.C. 112, ¶ 6. *See also B. Braun Medical, Inc.* v. *Abbott Lab.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). In considering whether there is 35 U.S.C. 112, ¶ 1, support for a means- (or step) plus-function claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. 112, ¶ 1, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (2) it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a means- (or step-) plus-function limitation. Note also: A rejection under 35 U.S.C. 112, ¶ 2, "cannot stand where there is adequate description in the specification to satisfy 35 U.S.C. 112, first paragraph, regarding means-plus-function recitations that are not, per se, challenged for being unclear." *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976). *See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 65 FR 38510, June 21, 2000.

[45] *See Hybritech Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.

[46] *See, e.g., Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin* v. *Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [*i.e.*, "in the same words"] to be sufficient").

[47] A claim which is limited to a single disclosed embodiment or species is analyzed as a claim drawn to a single embodiment or species, whereas a claim which encompasses two or more embodiments or species within the scope of the claim is analyzed as a claim drawn to a genus. *See also* MPEP § 806.04(e).

[48] 35 U.S.C. 112, ¶ 1. *Cf. Fields* v. *Conover*, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971) (finding a lack of written description because the specification lacked the "full, clear, concise, and exact written description" which is necessary to support the claimed invention).

[49] For example, if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372–73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). *Compare Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 (disclosure of software function adequate in that art).

[50] *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[51] *See, e.g., In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534–35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) ("One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.")

[52] *See, e.g., Fiers* v. *Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen.*, 927 F.2d at 1206, 18 USPQ2d at1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process.

[53] *See, e.g., Amgen*, 927 F.2d at1206, 18 USPQ2d at 1021 ("A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.") (citations omitted). In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor's idea of the invention. *Burroughs Wellcome Co.* v. *Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994). Reduction to practice in effect provides the only evidence to corroborate conception (and therefore possession) of the invention. *Id.*

[54] *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

[55] *See, e.g., Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326–27 (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteriod in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary

to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description."); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of "inert fluid" broadly.). However, in *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 USPQ2d at1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application.

[56] *See, e.g., Eli Lilly.*

[57] For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. *Cf. In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

[58] *See Wertheim*, 541 F.2d at 263, 191 USPQ at 97 ("[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.").

[59] *See* MPEP §§ 714.02 and 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure.").

[60] *See, e.g., In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be "not permanently fixed" to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.).

[61] *See, e.g., In re Robins*, 429 F.2d 452, 456–57, 166 USPQ 552, 555 (CCPA 1970) ("[W]here no explicit description of a generic invention is to be found in the specification * * * mention of representative compounds may provide an implicit description upon which to base generic claim language."); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads).

[62] *See, e.g., In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.""") (citations omitted).

[63] When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt* v. *Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998).

[64] *See, e.g., Johnson Worldwide Associates Inc.* v. *Zebco Corp.*, 175 F.3d at 993, 50 USPQ2d at 1613; *Gentry Gallery, Inc.* v. *Berkline Corp.*, 134 F.3d at 1479, 45 USPQ2d at 1503; *Tronzo* v. *Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833.

[65] *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

[66] *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

[67] *See Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

[68] *See In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

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## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Revision of Currently Approved Information Collection; Comment Request

**AGENCY:** Corporation for National and Community Service

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (hereinafter "Corporation"), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning the proposed revision of its Voucher and Payment Request Form (OMB #3045–0014).

Copies of the forms can be obtained by contacting the office listed below in the address section of this notice.

**DATES:** Written comments must be submitted to the office listed in the ADDRESSES section by March 6, 2001.

**ADDRESSES:** Send comments to Levon Buller, National Service Trust, Corporation for National and Community Service, 1201 New York Ave., NW., Washington, DC 20525.

**FOR FURTHER INFORMATION CONTACT:** Levon Buller, (202) 606–5000, ext. 383.

**SUPPLEMENTARY INFORMATION:** The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

#### Background

The Corporation supports programs that provide opportunities for individuals who want to become involved in national service. The service opportunities cover a wide range of activities over varying periods of time. Upon successfully completing an agreed-upon term of service in an approved AmeriCorps program, a national service participant—an AmeriCorps member—receives an "education award". This award is an amount of money set aside in the member's name in the National Service Trust Fund. This education award can be used to make payments towards qualified student loan or pay for educational expenses at qualified post-secondary institutions and approved school-to-work opportunities programs. Members have seven years in which to draw against any unused balance.

The National Service Trust is the office within the Corporation that administers the education award